

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware
corporation,)

Plaintiff,)

v.)

DEXCOM, INC., a Delaware corporation,)

Defendant.)

C.A. No. 05-590 (GMS)

REDACTED PUBLIC VERSION

DECLARATION OF WALTER BRATIC

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ABBOTT DIABETES CARE, INC.)	
a Delaware corporation,)	
)	
Plaintiff,)	
)	
)	
vs.)	CASE NO. 05-590 (GMS)
)	
DEXCOM, INC.,)	
A Delaware corporation,)	
)	
)	
)	
Defendant.)	

DECLARATION OF WALTER BRATIC

I, Walter Bratic, declare:

1. I am a Vice President of CRA International, Inc. ("CRA"). I am a Certified Public Accountant licensed to practice in the state of Texas. A copy of my resume, including my current and past employment and professional affiliations, a list of my testimony experience for the past four years, and a list of my publications in the past ten years, is included in Exhibit 1 to this declaration. I have over 20 years experience in evaluating economic damages. During my career, I have worked on many matters in the pharmaceutical and medical devices industries, including matters wherein I have been asked to evaluate the issue of irreparable harm.

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2. I have been retained by the law firm of Winston & Strawn LLP, counsel for Abbott Diabetes Care, Inc. ("Abbott") in this matter. CRA is being compensated at my standard rate of \$595 per hour for all of my work performed in connection with this matter. CRA's compensation is not contingent upon the outcome of this litigation or the opinions expressed herein.

Background

3. Diabetes is a condition that is relatively common, with an estimated 20.8 million people in the United States, or 7% of the population, who have diabetes.¹ One method of therapy that is common in controlling the symptoms of diabetes is to maintain blood glucose at near-normal levels.² Blood glucose meters are used by patients with diabetes to routinely check their blood glucose levels. These meters are typically used by placing a drop of blood from a finger stick onto a test strip, which is measured by the device.³ One of the limitations of this method is that it provides patients with only a snapshot of their glucose levels at any particular point in time, and, of course, pricking the finger is painful.

4. Abbott is currently developing the FreeStyle Navigator™ Continuous Glucose Monitoring System (the "FreeStyle Navigator"), a system designed to discreetly measure glucose levels as frequently as once per minute without the use of traditional blood glucose testing strips.⁴ The system involves a sensor attached to a plastic sensor mount with adhesive to adhere to the skin (similar to a patch). The sensor is placed just under the skin by a disposable self-insertion device, and a transmitter connects directly to the sensor. A small handheld device receives information wirelessly from the sensor / transmitter every minute. The receiver is designed to display glucose values, directional glucose trend arrows, and rate of change.⁵ In the application submitted to the Food and

¹ <http://www.diabetes.org/about-diabetes.jsp>

² "Continuous Glucose Monitoring: Innovation in the Management of Diabetes" New England Healthcare Institute, March 2005, page 20.

³ <http://www.diabetes.org/type-1-diabetes/blood-glucose-checks.jsp>

⁴ <http://www.abbottdiabetescare.com/freestylenavigator/qa.aspx>

⁵ <http://www.abbottdiabetescare.com/freestylenavigator/qa.aspx>

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Drug Administration (the "FDA"), Abbott is actively seeking approval for the FreeStyle Navigator as a replacement for traditional finger-stick therapy.⁶

5. In March 2005, DexCom Inc. ("DexCom") filed an application with the FDA for pre-market approval of a short-term continuous glucose monitoring system that is similar to the FreeStyle Navigator called DexCom STS.⁷ Similar to the FreeStyle Navigator, DexCom STS includes a sensor which is inserted just under the skin where it is held in place by an adhesive to the skin.⁸ Also similar to the FreeStyle Navigator, a hand held receiver receives information wirelessly from the sensor/transmitter on a frequent basis, and provides glucose values and glucose trend information.⁹ DexCom's management anticipates that DexCom STS will not be indicated for use as a substitute for single-point finger stick devices.¹⁰

6. During my research on this matter I identified a glucose monitoring system manufactured by Medtronic, Inc. called the Guardian RT. The Guardian RT system utilizes a glucose sensor that is inserted under a patient's skin and measures glucose levels of interstitial fluid up to every five minutes.¹¹ The glucose readings are then sent by a transmitter to a handheld monitor. The Guardian RT has a different configuration than do the FreeStyle Navigator and DexCom STS systems, in that the transmitter which relays glucose information to the portable receiver is connected to the glucose sensor by a wire.¹² The Guardian RT's configuration is less desirable than the configurations of the FreeStyle Navigator and DexCom STS systems because the wire can snag on clothing and is not convenient for users engaged in physical activity. The FDA approved the Guardian RT as an adjunct therapy for measuring glucose levels in

⁶ <http://www.drugtopics.com/drugtopics/content/printContentPopup.jsp?id=129077> (Occasional finger sticking will be necessary for calibration only)

⁷ DexCom 10-Q filed 11/1/2005, page 11.

⁸ <http://www.DexCom.com/sts.php>

⁹ <http://www.DexCom.com/sts.php>

¹⁰ DexCom 10-Q filed 11/1/2005, page 16.

¹¹ http://www.medtronic.com/UK/downloadablefiles/guardian_rt.pdf

¹² http://www.medtronic.com/UK/downloadablefiles/guardian_rt.pdf

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September 2005.¹³ I understand that the Guardian RT is only available in limited geographic areas.¹⁴

7. The distinction between devices approved or not approved to replace traditional finger-stick therapy is significant. A report issued by the New England Healthcare Institute has described designation as a replacement therapy as “critical” to the successful adoption of continuous glucose monitoring therapy.¹⁵ This report also stated that one obstacle continuous glucose monitoring therapy devices face in receiving a replacement therapy designation is achievement of a satisfactory level of point-in-time accuracy.¹⁶ This is an issue that Abbott has sought to resolve with respect to the FreeStyle Navigator. For example, in an October 2004 article appearing in Drug Topics, Abbott pointed out that clinical trial results involving the FreeStyle Navigator resolved some accuracy issues the FDA has raised about other glucose monitoring systems.¹⁷

Summary of Patent Infringement Action

8. On August 11, 2005, Abbott filed a patent infringement action against DexCom alleging that the DexCom STS will infringe four Abbott U.S. patents when made, used, offered for sale, or sold by DexCom. Abbott intends to seek injunctive relief in Court to prevent DexCom from launching its allegedly infringing product.

9. I have been asked to determine whether Abbott would suffer irreparable harm if the DexCom STS system were introduced to the market prior to the introduction of the FreeStyle Navigator system. Based on the information that I reviewed to date, I have been asked to prepare this declaration containing my opinions in support of Abbott’s response to DexCom’s Motion to Stay Pending Reexamination of the Patents-

¹³ “Medical device company announces FDA approval of glucose monitoring system” Medical Devices & Surgical Technology Week, September 11, 2005.

¹⁴ <http://www.minimed.com/products/guardianrt/availability.html>

¹⁵ “Continuous Glucose Monitoring: Innovation in the Management of Diabetes” New England Healthcare Institute, March 2005, page 33.

¹⁶ “Continuous Glucose Monitoring: Innovation in the Management of Diabetes” New England Healthcare Institute, March 2005, page 33.

¹⁷ <http://www.drugtopics.com/drugtopics/content/printContentPopup.jsp?id=129077>

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in-Suit. I may supplement my opinions as additional information becomes available to me in this matter.

Opinions

10. Based on my experience in the pharmaceutical and medical devices industries, it is my opinion that Abbott very likely would suffer irreparable harm if DexCom STS were introduced into the diabetes treatment market prior to the introduction of the FreeStyle Navigator.

11. It is well established in the medical device and pharmaceutical industries that the first company to launch an innovative product will capture a significant amount of the market and retain substantial market share even after the launch of competing products. The first to launch will immediately capture a significant market share as patients that previously relied on finger-stick devices switch to new technology. Additionally, the first to launch will enjoy the benefits of having its product linked to life changing technology even after the launch of competing products that use similar and even improved technology.

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14. DexCom's launch of its product before FreeStyle Navigator would make it difficult, if not impossible, to quantify Abbott's damages. DexCom's STS system would be the first product to reach the market that measures glucose frequently and repeatedly in a configuration similar to the FreeStyle Navigator. As a result of DexCom being first to market, the FreeStyle Navigator would lose its competitive advantage associated with its superior product configuration. The first product to launch will capture a large market share as patients switch from finger-stick technology, and consumers will associate the first widely available product with the new technology. Also, once a customer initially purchases a system such as the DexCom STS, it is likely that the customer will stay with that system and continue to purchase the disposable sensors on an ongoing basis because of the cost of switching to an alternative system (i.e., buying the transmitter and receiver) and the time associated with learning how to use a different system.

15. At the time of the injunction hearing, the economic and financial issue that is being evaluated is determination of the permanent, non-compensable damages the

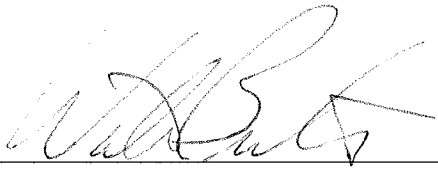
¹⁸ Declaration of Timothy Goodnow, March 10, 2005, page 4.

¹⁹ Declaration of Timothy Goodnow, March 10, 2005, page 4.

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plaintiff will suffer if injunctive relief is not granted. These damages clearly are focused on permanent impairment to be sustained by the plaintiff. At the time of trial, the economic and financial issue that is being evaluated is quantification of the direct actual and consequential monetary losses sustained as a result of alleged infringing activities. Calculating the lost profits and reasonably royalties, if any, at the time of trial on the merits of the case is different from determining the potentially broad, non-compensable consequences the plaintiff will suffer if no injunctive relief is granted.

March 10, 2006



Walter Bratic

CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

John W. Shaw
YOUNG CONAWAY STARGATT & TAYLOR LLP
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on March 22, 2006 upon the following individuals in the manner indicated:

BY HAND

John W. Shaw
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1000 West Street, 17th Floor
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Wilmington, DE 19899-0391

BY FEDERAL EXPRESS

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/s/ James W. Parrett, Jr.

James W. Parrett, Jr. (#4292)